

**5th meeting of the OIE Regional Commission for the Americas Working group on Risk
Analysis
Mexico D.F., November 26-30, 2001**

Participants

José Naranjo – SAG Chile
Eduardo Serrano –OIRSA
Ken Forsythe – APHIS United States
Randy Morley – CFIA Canada
Alejandro López – Panaftosa
Mairo Urbina – ICA Colombia
Assad Heneidi – SENASICA Mexico

Observer

Carlos Julio Jaramillo – Mexico

Coordinators:

Emilio Gimeno – OIE Regional Office for the Americas
Cristóbal Zepeda – OIE Collaborating Center for animal disease surveillance systems and risk analysis

Agenda

1. Review and approval of the agenda
2. Review of the group's work
3. Analysis of the OIE Code chapter section on risk management (articles 1.3.2.5 and 1.3.2.6)
4. Analysis of the OIE Code chapter section on risk communication (article 1.3.2.7)
5. Review of agreements from last meeting
6. Strategy for the presentation during the next OEI Regional Commission for the Americas Meeting

Welcome

Dr. Carlos Julio Jaramillo Animal disease surveillance sub-director of the General Directorate for Animal Health in Mexico welcomed the group on behalf of Dr. Javier Trujillo Arriaga Director in Chief of the National Service for Agrifood Health, Safety and Quality (Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria, SENASICA).

Review and approval of the agenda

The group reviewed the agenda. It was agreed to include a discussion on the seminar that will be held previous to the COSALFA meeting.

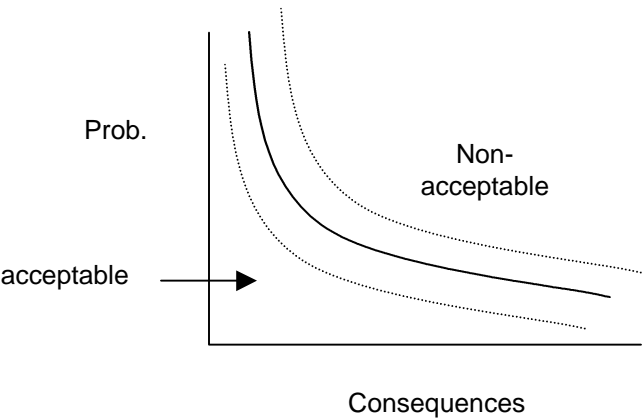
José Naranjo proposed that it would be useful if the group reviewed, possibly in a next meeting, the risk analysis proposal developed by Australia. Another important topic would be the use of risk analysis in mutual status recognition among countries.

Review of the group's work

Cristóbal Zepeda presented a summary of the group's work in benefit of new members and observers.

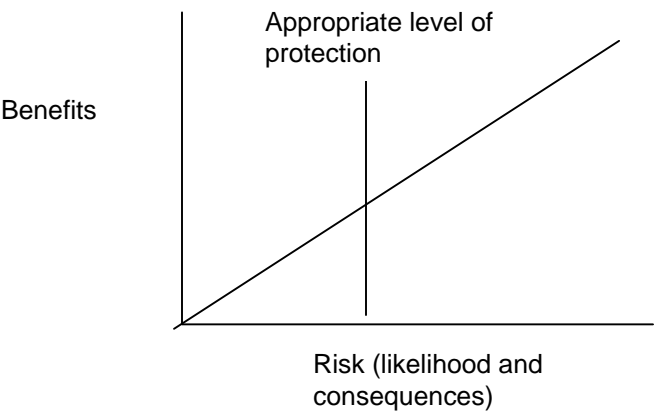
Analysis of the OIE Code chapter section on risk management (articles 1.3.2.5 and 1.3.2.6)
Principles of risk management

Risk Management assumes that the appropriate level of protection (ALOP) is previously defined. Risk management is directly linked to the ALOP. One approach to look at this is illustrated in the following diagram.



The intersection point of the probability (release and exposure) and the consequences can be placed on one side or the other of an imaginary line representing the ALOP.

Another way to look at this is a diagram in which risk (likelihood and consequences) are on the x-axis and net benefits of importation on the y-axis.



A point above the diagonal line would be acceptable in principle, given that the benefits would exceed the risk (likelihood and consequences). There are several interpretations of the SPS Agreement, some of them mention that the consideration of benefits in the decision process is not allowed. A topic under discussion is the extent of the consequences that should be considered (only consequences to the relevant industry or multi-market consequences).

Other interpretations of the SPS Agreement point out that the ALOP must be determined only on the basis of risk and its application should be consistent. This could be translated as a vertical line on the graph.

Risk is dependent on the volume of trade, as the volume increases risk increases. Additionally uncertainty needs to be considered, therefore we are not talking about points on the graph but ranges.

Another factor to consider is consistency. Can we have a single ALOP or can different values be used for each industry (i.e. one for beef, another one for poultry, etc.)? Some SPS Agreement interpretations indicate that a single ALOP has to be established. An opposing argument is based on the way trade tariffs are established within WTO, there are different tariffs for different products, following the same logic different ALOPs could be established.

The SPS Agreement does not specify how to establish the appropriate level of protection. This is a prerogative of the importing country, nevertheless the process by which it is established must be transparent and applied in a non-discriminatory fashion.

The accumulation of risk must be considered. This means that if several decisions implying risk accumulate, the overall likelihood of occurrence increases.

New Zealand establishes its ALOP based on an insignificant risk, if it is deemed "not insignificant" the process is iterated with additional mitigation measures. The Australian document proposes a level of acceptability based on probability and consequences.

The main problem in defining the ALOP is that there are no legal precedents at the WTO dispute settlement process on which to assess the validity of the different SPS Agreement interpretations.

Although several countries have defined their ALOP in a pragmatic way through the establishment of import requirements, in most cases their basis is not transparent and may not withstand scrutiny.

A problem that the group detected is that most risk analysis studies stop at the release assessment step, very few consider exposure assessment and fewer still consider consequences. This means that several countries determine their ALOP based on probability of occurrence and not on risk.

The group recognizes that on occasion quantifying consequences may not be achievable due to the lack of information. Nevertheless it is acceptable to conduct a consequence assessment in a descriptive way.

Most risk assessments are based on a set of initial risk reduction measures, this does not have to be necessarily this way. A study without mitigation measures is based on the status quo of the programs in the respective countries without additional mitigation measures.

The result of the disputes that have resolved at the WTO level indicate that the measures applied did not correspond with the findings of the risk assessment and were declared inappropriate. Therefore, it is essential that the application of measures has a direct correlation with the risk assessment results.

The group will develop a decision matrix to serve as a guide for countries. The existing examples such as the Australian document, USDA-PPQ's document, OIRSA's proposal and others that may exist will be circulated among the group.

Randy Morley handed-out several documents on risk management and communication. In particular he brought the attention of the group on an ISO document containing definitions related with risk and the discrepancies that exist with those used in the OIE Code.

The Code indicates that the sanitary measures of choice for risk management should be those in the OIE Code and the Manual of Standards for Diagnostic Tests and Vaccines. If a country wishes to apply different measures these should be scientifically sustained through a risk assessment.

Option evaluation. Risk management has two components: an analytical one assessing the efficacy of risk reduction measures and a second one related to decision-making.

Monitoring and review. This is the process by which the veterinary service in the importing country verifies and reviews the application of mitigation measures (both those applied at origin as well as those applied at destination). This is directly related with the Control, Inspection and Approval Procedures established in the SPS Agreement.

The responsibility for the application of most of the measures lies with the veterinary service of the exporting country. Verification is a prerogative of the importing country and is the basis for the mutual trust required in every export certification process.

Monitoring and review must include a review of the risk assessment in the light of new information.

Analysis of the OIE Code chapter section on risk communication (article 1.3.2.7)

The Spanish version of the Code uses interchangeably the term information referring both to risk communication and risk information. The group suggests that the heading of the article should be “Comunicación del riesgo” and that the word information be replaced by communication in accordance with the English version.

The group believes that there are conceptual differences between information and communication. The communication process is a multidirectional process involving all interested parties.

The Code only mentions risk communication principles. The group proposes to develop a section dealing with risk communication components, recognizing that the support of communication specialists will be needed. The group identified communication specialists in the different countries and organizations in the region that could help in the development of this section.

Two actions are identified: develop a proposal for an Article 1.3.2.8 on risk communication components and develop a guide in greater depth for use by countries.

There are different steps in risk communication. Communication includes the import request, gathering relevant information for the risk analysis and the communication of results with the interested parties.

Part of the risk communication strategy is the identification of the parties involved and the establishment of the basis for communication depending on the characteristics of each audience (general public, risk analysts, legal analysts, risk managers and others).

It is desirable that risk analyses are submitted for impartial peer review. The range of reviewers can vary according to the nature and complexity of the study. Scientific critique ensures consistency of the study prior to its release to the general public.

Review of agreements from last meeting

Risk analysis handbook (OIE Working group). The handbook has two broad sections; the first one is general and deals with the SPS Agreement and the OIE Code chapter on risk analysis, the second part deals in a very detailed way with quantitative risk analysis. It is foreseen that the handbook will be ready next year. Even though the handbook is almost ready the OIE working group developing it does not feel it is ready for distribution outside their group. Members from our group that have seen it feel that it will be a very important tool for several reasons: on one hand it gathers in a single document a great deal of information currently dispersed and on the other hand given that this is an OIE sponsored activity, its distribution to all member countries is ensured. The handbook must be included within the group's training strategy.

AFFA Australia recently published a document on Guidelines for Import Risk Analysis. The group should review it and decide if it should be included in the reference section of the website.

Report to the OIE Regional Commission for the Americas and the Director General informing on the group's work. Dr. Emilio Gimeno sent a note to the Director General and the Regional Commission.

Risk analysis model for the occurrence of Bovine Spongiform Encephalopathy (BSE) in the region. Alejandro López compiled several documents from the region and will send them to be included on the website by January 15.

A draft methodological proposal for BSE risk assessment was presented. The proposal is based on the OIE Code. This work raised doubts on certain recommendations and their relationship with the occurrence of the disease in cattle or in humans. The proposal will be sent to the group for review.

Strategy for the presentation during the next OIE Regional Commission for the Americas Meeting

- a) Based on the OIE survey on the use of risk analysis, the results for the region will be analyzed separately. This will provide a clearer vision on the status of risk analysis in the veterinary services. These results will be presented during the OIE Regional Commission for the Americas meeting.
- b) Mexico's Animal Health Director General submitted a request that the group includes in its agenda the topic "risk analysis study applied to meat, products and by-products in relation to Newcastle disease".

The group discussed if this proposal fits within the mandate of the group. In principle the group's mission is to guide and support countries in the development of their risk analysis capabilities by:

1. Interpreting the Risk Analysis Chapter in the OIE Code
2. Training in risk analysis methods
3. Developing practical guidelines for risk analysis
4. Providing methodological guidance for risk analysis studies
5. Providing methodological review of risk analyses submitted for consideration

The group can provide methodological review of risk analyses but does not conduct specific studies

- c) Results from the work of the group will be presented during the OIE Regional Commission for the Americas (website and training activities). The proposed agenda for group will be presented with the objective of obtaining a clear mandate from the Commission.

- d) The group identified the following topics for future work:
- Development of a practical guide for risk analysis
 - Methodological proposal for risk analysis on BSE, Newcastle disease and classical swine fever
 - Development of a proposal for corrections to the Spanish version of the Code
 - Development of principles and strategies on risk communication
 - Development of a proposal for the addition of an article 1.3.2.8 on risk communication components
 - Coordination with OIE for the translation of the risk analysis handbook into Spanish developed by the OIE Ad hoc group
 - Development of training materials based on the risk analysis handbook

Pre-COSALFA seminar

The seminar is two and-a-half days long and will be held in Salvador Bahia, Brazil on a date to be determined during the first quarter of 2002. The audience will be Chief Veterinary Officers. The topic for the seminar will be on risk analysis. Alejandro López will propose a tentative agenda for the group’s review.

Agreements

Gather a list of risk analyses done in the region and post it on the website.	Emilio Gimeno will ask countries a list of RA studies. A note was sent during the meeting.
Modify the risk analysis process diagram to include risk communication and correct the term monitoring and review.	Cristóbal Zepeda January 31
Compile the idiomatic problems in the RA chapter and propose through the Regional Commission for the Americas a correction to the Code in its Spanish version.	Cristóbal Zepeda January 31
Compile different decision matrices and development of a proposal fro the Americas.	<ul style="list-style-type: none"> - Australia Pepe Naranjo - Canadá Randy Morley Dec 31 - APHIS-PPQ Ken Forsythe Dec 31 - Geographical BSE risk Alejandro López Dec 31
Adapt OIRSA’s proposal in accordance to the current version of the OIE Code	Cristóbal Zepeda January 31
Review and comments on the adapted proposal	Group. Feb 28
Development of the group’s proposal for risk analysis	March 30
Provide the risk management and communication documents in electronic format	Randy Morley Jan 15
Send the BSE risk analysis proposal Comments back to Alejandro López	Alejandro López Dec 15 Group March 1

Agenda proposal for the COSALFA seminar	Alejandro López Dec 21
Comments from the group	Group Jan 15

The group thanks Mexico’s Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) and the Representation of Panamerican Health Organization for hosting the meeting.